



Food and Drug Administration
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January 12, 2015

TANGO₃, LLC
C/O Ms. Lori Holder
Regulatory Affairs Consultant
141 Citizens Boulevard
Simpsonville, Kentucky 40067

Re: K140984

Trade/Device Name: TANGO₃ Water Storage Tank with Ozone Disinfection System
Regulation Number: 21 CFR 876.5820
Regulation Name: Hemodialysis System and Accessories
Regulatory Class: II
Product Code: FIN
Dated: December 11, 2014
Received: December 12, 2014

Dear Ms. Holder:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

Tejashri Purohit-Sheth, M.D.

Tejashri Purohit-Sheth, M.D.
Clinical Deputy Director
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Erin I. Keith, M.S.
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Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K140984

Device Name

TANGO3 Water Storage Tank with Ozone Disinfection System

Indications for Use (Describe)

The TANGO3 Water Storage Tank with Ozone Disinfection System is intended to be used for disinfection of the water distribution system of a dialysis facility. The tank of the TANGO3 is also used as the water holding tank of the distribution system. The disinfection process is completely automated. Ozone concentration during disinfection is between 0.2 ppm and 0.3 ppm. Weekly disinfection cycles should be for four periods of 30 minutes with adequate water flushes between them and after the last cycle. In addition to the weekly disinfection cycle, a 45 minute disinfection cycle with at least two rinse cycles may also be performed multiple times weekly for additional reduction of bioburden as determined by user facility monitoring. At the end of disinfection, the distribution loop will have less than 0.1 mg/l. (0.1 ppm) of ozone, in accordance with AAMI/ISO 26722:2009 (4.2.13.5).

Type of Use (Select one or both, as applicable)

☐ Prescription Use (Part 21 CFR 801 Subpart D)

☒ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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K140984 510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

Submitter's Name: TANGO₃, LLC
141 Citizens Blvd.
Simpsonville, KY 40067
Telephone: (502) 722-8794

Contact person: Hugh Doss, Manager

Date of Summary: January 9, 2015

Device Name: TANGO₃ Water Storage Tank with Ozone Disinfection System

Device Classification Name: Hemodialysis System and Accessories (876.5820, FIN)

Device Classification: Class II

Device Description: The TANGO₃ Water Storage Tank with Ozone Disinfection System is specifically designed to facilitate ozone induction into the storage tank, and then distribute the ozonated water through the distribution water loop during non-operational hours of a hemodialysis facility. The storage tank of the TANGO₃ system is filled with adequate water and the ozone concentration is increased. The ozonated water is distributed throughout the distribution loop. The solution is recirculated throughout the distribution system. To complete the disinfection process, the system and distribution loop are then rinsed with adequate water. The described process is accomplished with 4 consecutive 30 minute cycles of ozone disinfection weekly. In addition, a disinfection cycle of 45 minutes multiple times per week may also be used for additional reduction of bioburden (as determined by user facility monitoring). After disinfection TANGO₃ will leave the distribution loop with less than 0.1 mg/l. (0.1 ppm) of ozone, in accordance with AAMI/ISO 26722:2009 (4.2.13.5).

System Description and Theory of Operation

The TANGO₃ Water Storage Tank with Ozone Disinfection System consists of the following components: a heat regenerative desiccant air dryer at a 20 SCFH of air flow, a Corona discharge ozone generator that produces a working concentration of 0.3ppm of ozone, a venturi based injection system, HDPE or Stainless Steel water storage tank, an off gas ozone destruct system, a multi-stage centrifugal distribution pump (dual distribution pumps are offered as an option), and a main controller and operator's interface. Sensors incorporated into the system include return and output flow sensors, an ozone sensor, a level sensor, a conductivity sensor, and an atmospheric ozone detector. Fluid contacting materials include: Stainless Steel 300 Series, High Density Polyethylene (HDPE), Lexan® (Polycarbonate), Acrylic (PMMA), Teflon® (PTFE), Viton® (FKM), Kynar® (PVDF), and PVC. The System produces a dissolved ozone concentration of 0.20 ppm to 0.30 ppm during the disinfection process.

The TANGO₃ System has been designed to meet the applicable requirements of the following voluntary standards:

- AAMI /ANSI RD52:2004 - Dialysate for hemodialysis
- AAMI/ANSI RD62:2006 - Water treatment equipment for hemodialysis applications
- AAMI/ISO 26722:2009 - Water treatment equipment for hemodialysis applications and related therapies

Ozone is produced in a flat gas stream which results in low energy consumption and high ozone concentration. Energy consumption is less than 7 kW per kilo ozone produced.

The ozone disinfection process is derived through the generator located on the front of the device. Atmospheric air passes through silica beads removing humidity from the air. The air then passes through an air dryer to additionally remove all remaining moisture from the air. The dry air passes between two electrode plates consisting of high current. To prevent the air from breaking down electrically along a simple line of rupture or spark, a sheet of glass is placed between the metal plates. By this means the air is made to break down electrically throughout thus greatly increasing the amount of ozone produced.

The air in the system is not pressurized but operates under a vacuum produced when the ozone recirculation pump is operating. The pump uses the purified water from the storage tank to pressurize the water. Then the water passes through a venturi creating a vacuum which will pull atmospheric air through the acrylic tube with silica gel, through the air dryers, and then through the generating chamber. The ozone gas is mixed with the purified water at the venturi and diffused into the holding tank. The ozonated water is then distributed from the holding tank to the distribution loop through the distribution pump and returns back to the storage tank. The return loop is monitored for dissolved ozone level achieving a level of 0.2 ppm to 0.3 ppm. Upon completion of the disinfection dwell time, a flushing phase is activated to destroy the residual ozone prior to use with patients.

To protect the distribution piping and well as other water contacting materials, a low level of ozone is used. Laboratory testing has proven a 6 log reduction of microbiological contamination when using dissolved ozone concentration levels between 0.2 ppm to 0.3 ppm while showing no immediate effect on PVC distribution piping.

Operation Overview

Three operational modes are provided: Dialysis, Maintenance, and Disinfection. The system is set to dialysis mode when the water system is being used for dialysis. The system is set to maintenance mode to allow for manual control of the system. Ozone product only occurs in disinfection mode. A description of the disinfection process follows.

The disinfection process is divided into the following phases, as shown above:

- 1) Ozonation: During this phase the ozone generator is on and ozonated water is being recirculated through the loop.
- 2) Loop and Tank Emptying: Once the ozonation phase is complete a valve will be actuated and the returning flow will go to drain instead of returning to the tank. The distribution pump will be kept on until the LOW TANK level is detected. At this point, the distribution pump, ozone generator and recirculation pump will be turned off. The tank drain valve will open, allowing the tank to empty by gravity.

- 3) Tank and Loop Refill: After the loop and tank are empty, TANGO₃ will allow adequate water to enter the storage tank. Once the TOP FLOAT level is detected, no more water will be allowed to enter the tank.
- 4) During the weekly disinfection cycle, steps 1) through 3) will be repeated for each cycle.
- 5) Ozone Destruction: A flushing process will be done with non ozonated water until the ozone sensor detects that the level of ozone residual complies with the AAMI requirements

To avoid the possibility of dissolved O₃ in the distribution loop while water is being used for other purposes, the system has two (2) flow meters to measure the input and the output of the storage tank. If those two (2) readings are not equal the ozone generator and the distribution pump will be turned off. In addition, daily manual checks may be performed to assure the absence of ozone in the loop prior to the beginning of the dialysis treatment using a properly calibrated digital colorimeter.

The presence of ozone in the room will also be monitored using an ambient ozone sensor and/or ambient ozone detection badges. Visual and audible alarms will be given if the levels are above normal OSHA and EPA exposure values.

Intended Use: The TANGO₃ Water Storage Tank with Ozone Disinfection System is intended to be used for disinfection of the water distribution system of a dialysis facility. The tank of the TANGO₃ is also used as the water holding tank of the distribution system. The disinfection process is completely automated. Ozone concentration during disinfection is between 0.2 ppm and 0.3 ppm. Weekly disinfection cycles should be for four periods of 30 minutes with adequate water flushes between them and after the last cycle. In addition to the weekly disinfection cycle, a 45 minute disinfection cycle with at least two rinse cycles may also be performed multiple times weekly for additional reduction of bioburden as determined by user facility monitoring. At the end of disinfection, the distribution loop will have less than 0.1 mg/l. (0.1 ppm) of ozone, in accordance with AAMI/ISO 26722:2009 (4.2.13.5).

Legally Marketed Devices to which Equivalence is Claimed:

- TANGO₃ Water Storage Tank with Ozone Disinfection System K0903641

Descriptive Summary of Technological Characteristics and Those of the Predicate Device: The features of TANGO₃ are equivalent to the predicate device in terms intended use, technological characteristics, and operational characteristics as summarized in the following table:

PARAMETER	PREDICATE DEVICE: TANGO ₃ , LLC TANGO ₃ Water Storage Tank with Ozone Disinfection System K093641	PROPOSED DEVICE: TANGO ₃ , LLC TANGO ₃ Water Storage Tank with Ozone Disinfection System
Classification Name And Product Code	Hemodialysis System and Accessories FIN	Hemodialysis System and Accessories FIN
Intended Use	The TANGO ₃ Water Storage Tank with Ozone Disinfection System is intended to be used for disinfection of the water distribution system of a dialysis facility.	The TANGO ₃ Water Storage Tank with Ozone Disinfection System is intended to be used for disinfection of the water distribution system of a dialysis facility.
Indications for Use	The TANGO ₃ Water Storage Tank with Ozone Disinfection System is intended to be used for disinfection of the water distribution system of a dialysis facility. The tank of the TANGO ₃ is also used as the water holding tank of the distribution system. The disinfection process is completely automated. Ozone concentration during disinfection is between 0.2 ppm and 0.3 ppm. The distribution system will be exposed to ozone for one (1) period of 45 minutes and three (3) periods of 30 minutes with adequate water flushes between them and at the end, leaving the distribution loop without ozone.	The TANGO ₃ Water Storage Tank with Ozone Disinfection System is intended to be used for disinfection of the water distribution system of a dialysis facility. The tank of the TANGO ₃ is also used as the water holding tank of the distribution system. The disinfection process is completely automated. Ozone concentration during disinfection is between 0.2 ppm and 0.3 ppm. Weekly disinfection cycles should be for four periods of 30 minutes with adequate water flushes between them and after the last cycle. In addition to the weekly disinfection cycle, a 45 minute disinfection cycle with at least two rinse cycles may also be performed multiple times weekly for additional reduction of bioburden as determined by user facility monitoring. At the end of disinfection, the distribution loop will have less than 0.1 mg/l. (0.1 ppm) of ozone, in accordance with AAMI/ISO 26722:2009 (4.2.13.5).
Materials in Contact With Fluids	Stainless Steel, Teflon, PVC	Stainless Steel, Teflon, PVC, HDPE
Water Requirements: <i>Water Quality</i>	AAMI Quality	AAMI Quality
Environmental Limits: <i>Ambient Temperature</i> <i>Relative Humidity</i> <i>Ambient Ozone</i>	40° - 100° F (4.4° - 38° C) 10 – 80% < 0.1ppm (OSHA)	40° - 100° F (4.4° - 38° C) 10 – 80% < 0.1ppm (OSHA)
Contact Time	30 or 45 minute cycles	30 or 45 minute cycles
Frequency	As required	As required
Used during	Non-operational hours	Non-operational hours
Rinsing	Automatic with water	Automatic with water
Alarms	Audible and visible indicators	Audible and visible indicators
Gas Feed	Dried air, with heat regenerative desiccants	Dried air, with heat regenerative desiccants
Ozone Generator	Corona discharge	Corona discharge
Injection System	Venturi based	Venturi based
Storage Tank	Stainless Steel or compatible with ozone	Stainless Steel or compatible with ozone
Applicable Standards	AAMI RD 62	AAMI RD 62

Performance Data: The following performance data were provided in support of the substantial equivalence determination. The results from these tests show that the TANGO₃ performed as expected.

Reliability Validation Testing

Reliability testing has been conducted to ensure that all components of the system function as designed for the intended life of the TANGO₃. This testing included a validation of the software functions, including alarms. The system was tested to simulate 10 years of use.

The following table outlines the tests that were conducted as part of the reliability testing. All tests passed and demonstrated that the device works as intended.

Test	Evaluation or Test
O ₃ generation capability	<ul style="list-style-type: none"> ▪ O₃ level between 0.2 ppm and 0.3 ppm
O ₃ Calibration	<ul style="list-style-type: none"> ▪ No variation greater than 5%
Valves and dissolved ozone destruct	<ul style="list-style-type: none"> ▪ No valve related alarms should be observed ▪ Level of ozone not above 0 ppm
Pump	<ul style="list-style-type: none"> ▪ Loop velocity maintained at 4 ft/sec ± 10%
Ambient ozone	<ul style="list-style-type: none"> ▪ Ambient ozone readings on both automated ozone detector and badge
FMEA	<ul style="list-style-type: none"> ▪ Validate that a failure of critical components will be detected

Disinfection Validation

Testing was conducted to validate the disinfection performance of the ozone generator when used for water disinfection for dialysis and to determine the efficacy of O₃ to disinfect water to below contamination action levels (bacteria and LAL). Overall, results of the disinfection validation show that the disinfection effectiveness of TANGO₃ while keeping the water in the dialysis water distribution loop below AAMI RD 62:2006 action levels.

An overview of each test is provided in the table below.

Test	Organisms Tested
Disinfection of Clinically Relevant Waterborne Bacteria	<ul style="list-style-type: none"> ▪ <i>Acidovorax</i>, ▪ <i>Pseudomonas Aeruginosa</i>, ▪ <i>Burkholderia Cepacia</i>, ▪ <i>Brevundimonas Diminuta</i> ▪ <i>Mycobacterium Fortuitum</i>
Normal Inoculation (Simulated Use) Testing	<ul style="list-style-type: none"> ▪ <i>Acidovorax</i>, ▪ <i>Pseudomonas Aeruginosa</i>, ▪ <i>Burkholderia Cepacia</i>
Biofilm Reduction and Prevention Capability Testing	<ul style="list-style-type: none"> ▪ <i>Acidovorax</i> ▪ <i>Pseudomonas Aeruginosa</i> ▪ <i>Burkholderia Cepacia</i>
Elimination of Enveloped and Non-enveloped Viruses	<ul style="list-style-type: none"> ▪ Poliovirus Type 1 ▪ Rotavirus ▪ Herpes Simplex Virus Type 1
Fungi Elimination Efficacy	<ul style="list-style-type: none"> ▪ <i>Candida Tropicallis</i> ▪ <i>Aspergillus</i>

Field Testing

Field testing was performed in four (4) dialysis facilities with histories of water contamination. All four (4) facilities had documented water contamination issues and required periodic disinfection processes in order to maintain total bacterial counts and endotoxin levels below AAMI recommendations. This testing was conducted under a

standard protocol, which was reviewed and approved by the Institutional Review Board (IRB) of the facility at which the testing was conducted. The IRB determined that the testing was to be non-significant risk. Disinfection with the TANGO₃ System was performed based on the clinic's policies and procedures. Results show that TANGO₃ was able to maintain the water in the distribution loop below AAMI RD 62:2006 action levels.

Software Verification and Validation Testing

Complete software validation, verification, and performance testing was performed to confirm that the features worked correctly and that the Programmable Logic Controller, the Human Machine Interface, and the Ozone systems hardware functioned together as expected. Documentation was provided as recommended by FDA's Guidance for Industry and Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." The software for this device was considered a "moderate" level of concern since, prior to mitigation of hazards, a failure of the software could result in Minor Injury, either to a patient or to a user of the device.

Human Factors Testing

Human factors testing was conducted to verify that the user can safely operate the TANGO₃. Different ranges to set up parameters were entered, and the readability of screens and messages was evaluated. Proper recognition of visual and audible alarms was also verified.

Conclusion: The information and data provided in this 510(k) Notification establish that the TANGO₃ Water Storage Tank with Ozone Disinfection System is substantially equivalent to the legally marketed predicate device.